

SALK1520-2 (088802-8752)

09/042,488

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Evans et al.	Group Art Unit: 1633
Application No.: 09/042,488	Examiner: S. Kaushal
Filing Date: March 16, 1998	Applicant's Representative: Stephen E. Reiter
For: METHOD FOR MODULATING EXPRESSION OF EXOGENOUS GENES IN MAMMALIAN SYSTEMS, AND PRODUCTS RELATED THERE TO	

**Agenda for Telephone Interview on March 18, 2003****Discuss rejections under 35 USC § 112, first paragraph, in Office Action mailed 02/11/2003****I. Possession of the claimed invention**

- discuss grouping of claims and claim components in comparison to allowed claim 71
- discuss how the specification describes all features required by the present claims
  - in particular: (i) similarity of components of claims 50 and 67-70 to claim 71
  - (ii) similarity of components of claims 1 and 22-24 to claim 71

**II. Enablement**

- discuss support for all of the required elements of the claims as identified above
- discuss disclosure being commensurate with the scope of the claims
- discuss ease of substitution of specifically defined response element in place of ecdysone response element for one of skill in the art
- discuss potential cancellation of claims 72-77

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**CLAIM SUMMARY FOR SALK1520-2**

**Methods of gene regulation in isolated cells** (Claims 1, 3-9, 11-13, 15-24, 39, 40, 47-55, 57-69, 70, and 71)

Claims 1, 3-9, 11-13, 15-21, 39, 40, 47-49, 50-55, 57-66, 70, and 71 (independent in bold)  
– methods for modulating the expression of an exogenous gene in an isolated cell

Claims 22, 23, 67, and 68  
– methods of inducing the expression of an exogenous gene in an isolated cell

Claims 24 and 69  
– methods for the expression of a recombinant product detrimental to isolated host cells

**Methods of gene regulation in a mammalian subject** (Claims 72-77)

Claims 72 and 75  
– methods for modulating the expression of an exogenous gene in a mammalian subject

Claims 73, 74, 76 and 77  
– methods of inducing the expression of an exogenous gene in a mammalian subject

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Comparison of allowed claim 71 to other independent claims using isolated cells

Claim	exogenous gene components	relationship	modified receptor components
71 allowed	gene under the control of an <u>ecdysone</u> response element	modified ecdysone receptor binds to ecdysone response element in the presence of a ligand (optional silent partner) modified receptor has an altered binding specificity as compared to wildtype receptor	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
50	gene under the control of an <u>ecdysone</u> response element	modified receptor binds to ecdysone response element in the presence of a ligand (optional silent partner) modified receptor does not bind to endogenous response elements	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
67	gene under the control of an <u>ecdysone</u> response element	modified <del>ecdysone</del> receptor binds to ecdysone response element in the presence of a ligand (optional silent partner) modified receptor does not bind to endogenous response elements	receptor under control of an <u>inducible</u> promoter LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
68	gene under the control of an <u>ecdysone</u> response element	modified <del>ecdysone</del> receptor binds to ecdysone response element in the presence of a ligand (optional silent partner) modified receptor does not bind to endogenous response elements	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
69	gene under the control of an <u>ecdysone</u> response element	modified receptor does not bind to endogenous response elements	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
70	gene under the control of an <u>ecdysone</u> response element	modified <del>ecdysone</del> receptor binds to ecdysone response element in the presence of a ligand (optional silent partner) modified receptor has substantially no constitutive activity	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor

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1	gene under control of a specifically defined response element	modified ecdysone receptor binds to ecdysone response element in the presence of a ligand (optional silent partner)	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor receptor under control of an <u>inducible</u> promoter
22	gene under control of a specifically defined response element	modified ecdysone receptor binds to defined response element in the presence of a ligand (optional silent partner)	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
23	gene under control of a specifically defined response element	modified ecdysone receptor binds to defined response element in the presence of a ligand (optional silent partner)	LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor
24	gene under control of a specifically defined response element		LBD for ecdysteroid DBD from DNA-binding protein activation domain of a transcription factor

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